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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,523	12/23/1999	Richard B. van Breemen	21726/90386	7519

7590

02/25/2003

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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,523

Applicant(s)

BOLTON ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (Paper No. 20). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 December 2002 has been entered.

Receipt is acknowledged of an amendment on 03 December 2002 (Paper No. 21)

Status of the Claims

Claims 1-5 and 7-12 were pending in the application. Claims 1-5 and 7-12 were cancelled and new claims 13-29 were added in Paper No. 21. Newly submitted claims 24-29 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Claims 24-28 are drawn to a method for determining characteristics that are not predetermined of a mixture of compounds as opposed to the previously examined method for determining whether a single compound from a sample has predetermined characteristics. The examined invention requires the addition of a sample to a continuous flow of supportive solution, a limitation not found in claims 24-28. Similarly, claim 29 does not include the addition of a sample to a continuous flow of supportive solution. The method of claim 29 also requires NADPH unlike the examined invention.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 13-23 are pending and examined on their merits.

Withdrawn Rejections

1. All outstanding rejections are withdrawn in response to Applicants' cancellation of all rejected claims.

New Grounds of Rejection

The statutory basis for each of the following rejections not found below may be found in a prior office action.

New Grounds of Rejection – 35 U.S.C. 112, first paragraph

2. Claims 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter).

A. New claims 13-22 lack the claim limitations of maintaining a continuous flow of a supporting solution and adding the sample (compound or mixture of compounds) to the continuous flow of the supporting solution. The specification does not support the omission of this claim limitation.

B. New claims 13-23 are drawn to a method and kit for determining whether a compound or mixture of compounds is suitable for intended use as a drug or a natural product. The original claims were drawn to a method and kit for determining whether a compound (i.e. single compound) has a predetermined characteristic that would make it suitable for a specific purpose

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such as being a candidate for drug development. The specification does not support the recitation of “*intended use as a drug or a natural product*” or determining whether a mixture of compounds has a predetermined property that would make it (i.e. the mixture) suitable for a specific purpose. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

C. New claim 17 recites the limitation that the supportive solution “*facilitates the removal of compounds, or mixture of compounds and products of the reactions between the compound or mixture of compounds and the biological material, by washing them through the ultrafiltration chamber into the second solution.*” This newly introduced claim limitation is not supported by the disclosure as filed. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

D. New claim 21 recites the claim limitation “*...wherein the products of the reactions comprise metabolites, glutathione adducts, and small molecules to determine cellular absorption.*” This newly introduced claim limitation is not supported by the disclosure as filed. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

E. New claim 23 recites a claim limitation involving pore sizes that allow passage of compound(s) and reaction products through the membrane. The specification as filed does not support this claim limitation. The specification refers to results of interactions (compatible with cell absorption assays) and not products of reactions (incompatible with cell absorption assays). In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

3. Claims 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (written description).

The rejected claims are drawn to a method and kit comprising any compound or mixture of compounds having any intended use as a drug or natural product, any biological material, and any reaction between biological material and (test) compound(s). Applicants are required to

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describe the use of the claimed method and kit commensurate with the scope of the claims. The description of individual elements of the claimed invention without their involvement in the method or the kit is not sufficient to meet the written description requirement.

Applicants may show possession of the full scope of the claimed invention by way of representative examples which would indicate to one skilled in the art that Applicants possessed the full scope of the claimed invention. Applicants provide a small number of drugs (i.e. not representative of all drug classes whether the class is designated by structure and/or function such as tricyclic antidepressants, steroids, ACE inhibitors, anticholinergics, and statins, for example) and the predetermined characteristics of glutathione adduct formation, absorption into a single cell type, and catabolism by cytochrome P450 in the specification (i.e. not representative of suitability for all intended uses as a drug or natural product such as anesthetic, antibiotic, antineoplastic, sunscreen, or appetite suppressant). These representative samples are insufficient to convey to one skilled in the relevant art that Applicants possessed a method and kit that can be used to determine whether any compound or mixture of compounds is suitable for use as a drug or natural product.

New Grounds of Rejection – 35 U.S.C. 112, second paragraph

4. Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. Claim 13 recites the limitation "*compounds or mixture of compounds*" in line 4. There is insufficient antecedent basis for this limitation in the claim.
- B. Claim 17 recites the limitation "*compounds, or mixture of compounds*" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.
- C. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: cells that perform the absorption and compound(s) that would react to form metabolites glutathione adducts, and small molecules to determine cellular absorption.


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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner's normal schedule is four, ten-hour days per week including Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
09 February 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600